

Translation

PATENT COOPERATION TREATY

PCT/JP2003/015753



PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference NG004PCT	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/JP2003/015753	International filing date (day/month/year) 09 December 2003 (09.12.2003)	Priority date (day/month/year) 20 December 2002 (20.12.2002)
International Patent Classification (IPC) or national classification and IPC C12N 15/09, A01H 1/00		
Applicant INCORPORATED ADMINISTRATIVE AGENCY NATIONAL AGRICULTURE AND BIO-ORIENTED RESEARCH ORGANIZATION		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☒ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) 1 disc, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand 21 April 2004 (21.04.2004)	Date of completion of this report 23 August 2004 (23.08.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ The international application as originally filed/furnished
- ☐ the description:
- pages _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- pages _____, as originally filed/furnished
- pages* _____, as amended (together with any statement) under Article 19
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the drawings:
- pages _____, as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. 1, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis that of:
- a. type of material
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☒ filed together with the international application in computer readable form
 - ☐ furnished subsequently to this Authority for the purpose of search and/or examination
 - ☐ received by this Authority as an amendment* on _____
2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

* If item 4 in Box No. 1 applies, the listing and /or table(s) related thereto, which form part of the basis of the report, may be marked "superseded".

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-91	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-91	NO
Industrial applicability (IA)	Claims	1-91	YES
	Claims		NO

2. Citations and explanations

- Document 1: Y. Maruta et al., "Transgenic rice with reduced glutelin content by transformation with glutelin A antisense gene," *Molecular Breeding*, Vol. 8, pages 273-284 (2001)
- Document 2: A. Goossens et al., "Co-introduction of an antisense gene for an endogenous seed storage protein can increase expression of a transgene in *Arabidopsis thaliana* seeds," *FEBS Letters*, Vol. 456, pages 160-164 (1999)
- Document 3: W.T. Kim et al., "Nucleotide and primary sequence of a major rice prolamine," *FEBS Letters*, Vol. 231, pages 308-310 (1988)
- Document 4: S.V. Wesley et al., "Construct design for efficient, effective and high-throughput gene silencing in plants," *Plant Journal*, Vol. 27(6), pages 581-590 (2001)

Claims 1 to 15, 23, 53 to 58, 60, 62 to 68, 70 to 75, 77, 79 to 82, and 89

Document 1 cited in the international search report makes disclosures pertaining to the rice storage protein of glutelin, wherein an antisense technique is used to produce rice having a reduced glutelin content in the

seeds. Document 2 discloses a feature wherein 2S albumin content is decreased and arcelin-5 content is increased in the seeds of an *Arabidopsis* into which antisense DNA for the storage protein 2S albumin and an exogenous arcelin-5 gene are introduced, and indicates that it is likely that in many plants, the expression of exogenous genes could be increased by inactivation of a gene that encodes a major storage protein. Document 3 discloses a rice prolamine gene.

A technical concept wherein an antisense technique is applied to a seed storage protein, thereby reducing the expression of said seed storage protein, is known in the art, as disclosed in documents 1 and 2; thus, applying said technical concept to the prolamine which is a major storage protein for rice, disclosed in document 3, would be obvious to a person skilled in the art.

Accordingly, the inventions set forth in the above claims do not involve an inventive step in the light of documents 1 to 3.

Claims 16 to 22

Document 4 cited in the international search report discloses a technique wherein hairpin RNA for a plant is formed by joining a nucleic acid sequence derived from a target gene and a self-complementary nucleic acid sequence having a nucleic acid sequence that is complementary to said gene, and indicates that this technique is effective in reducing expression of said target gene.

A technical concept wherein an antisense technique is applied to a seed storage protein, thereby reducing the expression of said seed storage protein, is known in the art, as disclosed in documents 1 and 2; thus, applying said technical concept to the prolamine which is a major storage protein for rice, disclosed in document 3, and adopting the technique disclosed in document 4 as a

technique for reducing expression, would be obvious to a person skilled in the art.

Accordingly, the inventions set forth in the above claims do not involve an inventive step in the light of documents 1 to 4.

Claims 24, 33 to 46, 59, 61, 69, 76, 78, 83 to 88, 90, and 91

Document 2 discloses a feature wherein 2S albumin content is decreased and arcelin-5 content is increased in the seeds of an *Arabidopsis* into which antisense DNA for the storage protein 2S albumin and an exogenous arcelin-5 gene are introduced, and indicates that it is likely that in many plants, the expression of exogenous genes could be increased by inactivation of a gene that encodes a major storage protein. Document 3 discloses a rice prolamine gene.

Prolamine is a major storage protein of rice, and thus, when applying the technique disclosed in document 2 to rice, making the prolamine disclosed in document 3 the target for reduction of expression through the use of an antisense technique would be obvious to a person skilled in the art.

Accordingly, the inventions set forth in the above claims do not involve an inventive step in the light of documents 2 and 3.

Claims 25 to 32 and 47 to 52

Document 2 discloses a feature wherein 2S albumin content is decreased and arcelin-5 content is increased in the seeds of an *Arabidopsis* into which antisense DNA for the storage protein 2S albumin and an exogenous arcelin-5 gene are introduced, and indicates that it is likely that in many plants, the expression of exogenous genes could be increased by inactivation of a gene that encodes a major

storage protein. Document 3 discloses a rice prolamine gene. Document 4 cited in the international search report discloses a technique wherein hairpin RNA for a plant is formed by joining a nucleic acid sequence derived from a target gene and a self-complementary nucleic acid sequence having a nucleic acid sequence that is complementary to said gene, and indicates that this technique is effective in reducing expression of said target gene.

Prolamine is a major storage protein of rice, and thus, when applying the technique disclosed in document 2 to rice, making the prolamine disclosed in document 3 the target for reduction of expression through the use of an antisense technique, and adopting the technique disclosed in document 3 as a technique for reducing expression, would be obvious to a person skilled in the art.

Accordingly, the inventions set forth in the above claims do not involve an inventive step in the light of documents 2 to 4.

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VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

- (1) The use of the phrase "said complementary" in (A) of claim 16 is recognized as a typographical error for "said ... deriving from."
- (2) The use of the phrase "said complementary" in claim 25 is recognized as a typographical error for "said... deriving from."